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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,959	06/25/2001	Richard Ian Christopherson	DAVI139.001C1	2583

500 7590 09/08/2008

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/888,959	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2008 has been entered.

Claims 28-35 have been amended. Claims 28-40 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-34 are vague and indefinite by way of relying on Examples and Figures in the specification. Section 2173.05(s) of the MPEP states

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A)As drawn to the number of immunoglobulins within an array

Claim 29 embodies the method of claim 28 wherein the solid support contains a least one immunoglobulin specific for a single cell surface marker antigen[s] of a T cell, B cell or myeloid lineage selected from the recited group. The originally filed disclosure provides for the array comprising the immunoglobulins of claim 28, followed by a large array for distinguishing sub-populations of cells using antibodies against 33 CD antigens (page 61, lines 5-23). Thus, one of skill in the art would not reasonably conclude that the method of claim 29 would encompass the addition of "one or more" immunoglobulins as recited in claim 29, because the originally filed disclosure teaches distinguishing the sub-population using 33 CD antigens. Claims 30 to 34 rely 39 immunoglobulins selected from Table 8, 41 immunoglobulins selected from Table 4, 42 immunoglobulins selected from Table 5, 6 or 7, 44 immunoglobulins selected from Figure 7a and 52 immunoglobulins selected from Figure 8a. Examination of said figures indicates that the Table 8 describes an antibody dot array of 42 immunoglobulins, Table 4 describes an antibody dot array of 51 immunoglobulins, Tables 5, 6 and 7 describe antibody dot arrays of 49 immunoglobulins and Figure 7a describes and antibody dot array of 54 immunoglobulins. One of skill in the art would reasonably conclude that specific arrays of 39, 41, 42 and 44 immunoglobulins were not described in the specification as filed.

(B)As drawn to a "derivatized" solid support

Claims 28-33 have been amended to incorporate the limitation of "derivatized" solid support. The originally filed disclose described only a single derivatized solid support as nitrocellulose film on glass (page 62, line 5). One of skill in the art would reasonably conclude that application was not in possession of the instant method utilizing derivatized supports beyond that of nitrocellulose coated glass at the time of filing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 29 rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of Gruber et al (Journal of Immunological Methods, 1993, Vol. 163, pp. 173-179) in view of Wysocki and Sato (PNAS, 1978, Vol. 75, pp. 2844-2848, reference of the IDS filed April 29, 2003) and Delamarche et al (Science, 1997, Vol. 276, pp. 779-781).

Claim 28 is drawn to a method comprising providing a single assay device comprising a derivatized solid support having an array of immunoglobulins immobilized in discreet regions, wherein the immunoglobulins are specific for CD3, CD4, CD8, CD14, CD19 and CD56; contacting the biological sample containing leukocytes obtained from a human subject with said device,; and allowing leukocytes in said sample to bind to the immobilized immunoglobulins to form a pattern of binding on the derivatized solid support. Claim 29 embodies the method of claim 28 wherein the derivatized solid support further comprising at least one immunoglobulin selected from a group including CD16, CD25, CD38, CD45RO, CD45RA, CD57 and HLA-DR.

It is noted that the recitation of a method for distinguishing leukemia of a T cell, B cell or myeloid lineage has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does

not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is further noted that the phrase "determining the relative scale of the pattern of simultaneous binding with which the cell surface marker antigens CD3, CD4, CD8, CD14, CD19, and CD56 on the leukocytes have bound to the immunoglobulin molecules on the array, wherein the relative scale of the pattern of CD3, CD4, CD8, CD14, CD19, and CD56 binding on the array distinguished leukemia of T cell, B cell or myeloid lineage in the subject" is not given patentable weight when comparing the claims to the prior art as it simply expresses a mental conclusion.

The abstract of Gruber teaches the detection of the cell surface markers of CD3, CD4, CD8, CD14, CD19 and CD56, as well as CD16, CD25, CD38, CD45RO, CD45RA, CD57 and HLA-DR in whole blood. The abstract does not teach the use of a derivatized solid support comprising said immunoglobulins.

Wysocki and Sato et al teach that lymphocytes from a heterogeneous population can bind to a solid support coated with an antibody specific form a cell surface antigen (page 2844, first column, lines 15-17 after the abstract). Wysocki and Sato et al teach that this method is a simple and inexpensive alternative to flow cytometery (page 2844, first column, lines 6-13 after the abstract).

Delamarche et al teach a method of applying different immunoglobulins in a pattern on a elastomer coated solid support with high resolution(page 779, column 1 and column 2). Delamarche et al teach that the method is inexpensive and has high spatial definition and is inherently general, so that many assays in current use can be readily miniaturized without the need for lithographic equipment (page 781, second column).

It would have been prima facie obvious at the time the claimed invention was made to make a derivatized solid support by the method of Delamarche et al, wherein said solid support comprised the immunoglobulins CD3, CD4, CD8, CD14, CD19, CD56, CD16, CD25, CD38, CD45RO, CD45RA, CD57 and HLA-DR. One of skill in the art would have been motivated to do so by the teachings of Wysocki and Sato indicating that the method of binding leukocytes from whole blood to antibodies bound to a solid support was simple and inexpensive, and the

teachings of Delamarche et al regarding the microfluidic method of providing an antibody array with high spatial resolution which is economical to produce.

All other rejections and objections as set forth or maintained in the previous office action are withdrawn.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643